Body image and sexuality in head and neck cancer patients

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Chapter 5

Effect of stepped care on sexual interest and enjoyment in distressed head and neck cancer patients: a randomized controlled trial

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ABSTRACT

Introduction

A recent randomized controlled trial (RCT) in head and neck cancer (HNC) patients with psychological distress showed that a stepped care (SC) program targeting psychological distress compared to care as usual (CAU), is (cost)effective in reducing psychological distress.

Aim

The aim of the present study was to investigate whether SC can co-alleviate problems with sexuality. A secondary aim was to investigate whether the presence of an unmet sexual health need and having a psychiatric disorder (depression or anxiety) at baseline moderated any effect of SC on sexuality until one year follow-up.

Methods

HNC survivors (n = 134), randomized to SC or CAU, were assessed regarding their sexual interest and enjoyment before and after the intervention and at 3, 6, 9 and 12 months follow-up. Linear mixed models were used to evaluate differences in the course of sexual interest and enjoyment between SC and CAU.

Main Outcome Measure

The 'Sexuality' symptom subscale, part of the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire, Head and Neck Cancer-specific module.

Results

Of all patients 76.1% had an unmet sexual need at baseline, 24.6% had a psychiatric disorder (anxiety or depression). SC did not reduce problems with sexual interest and enjoyment at any of the follow-up measurements compared to CAU ($p = 0.85$). This was neither moderated by an unmet sexual health need at baseline ($p = 0.64$) nor by the presence of a psychiatric disorder at baseline ($p = 0.59$).

Conclusion

A substantial number of HNC patients have unmet sexual health needs. SC targeting psychological distress does not reduce problems with sexuality in these patients. Interventions specifically targeting sexuality are recommended.

INTRODUCTION

Sexual problems are highly prevalent in cancer patients and include changes in sexual function, activity and pleasure (e.g., vaginal dryness, erectile and orgasm dysfunctions, decreased sexual desire, arousal and enjoyment)[1,2]. These problems can lead to significant distress and are, besides other adverse (bio)psychosocial consequences (e.g., pain, anxiety, fatigue), among the most negative influences of cancer and its treatment on quality of life[1-3]. Even though the cancer is located outside the sexual organs, head and neck cancer (HNC) patients are at risk for developing intimacy issues or sexual problems[4,5]. The disruption of physiological, psychological and social functioning that accompanies HNC could all negatively impact sexuality directly, indirectly and reciprocally[1,2]. For example, treatment of HNC patients often results in visible facial disfigurement (e.g., scars or stoma in the neck), communication complications and other psychological and functional deficits (e.g., problems with smell, speaking and swallowing) that may interfere with intimate contact or sexual performance (e.g., kissing or oral sex)[4-8]. Thus, sexuality of HNC patients may be affected in a multidimensional manner.

However, sexuality is often overlooked, despite being an integral part of general health[5,8,9]. Only a limited number of studies have investigated sexuality among HNC patients. These studies indicate that HNC and its treatment have a negative impact on sexuality, especially immediately after oncological treatment, and particularly in those patients with high levels of distress, disrupted social functioning, extensive disfigurement and advanced tumor stages[7,8,10,11]. Sexuality was listed in the top three of the most bothersome symptoms among HNC patients[12]. Furthermore, over one-fifth of HNC patients who underwent a total laryngectomy expressed that their need for supportive care targeting sexual problems was not satisfactorily met[13]. These findings indicate that adequate screening and interventions are needed to help detect and address intimacy issues and sexual problems in HNC patients.

Recently, a randomized controlled trial (RCT) was conducted to investigate efficacy of stepped care (SC) directed at psychological distress compared to care as usual (CAU) in HNC and lung cancer (LC) patients with psychological distress[14,15]. The findings showed that SC significantly reduced psychological distress and improved quality of life, particularly in patients with a psychiatric disorder.

Poor functioning in the general life domain (e.g., low self-esteem, depression and neuroticism) may negatively affect the marital and sexual domain in cancer patients[11,16,17]. Given the significant association between psychological distress and sexual problems[8,11,16,17], it is important to understand how these co-existing symptoms can be alleviated. Therapeutic interventions targeting sexuality can improve psychological wellbeing[18], but it is still unknown

whether interventions targeting psychological distress also reduce sexual problems in cancer patients.

Although SC was not specifically directed at sexual problems, it is plausible that sexual interest and enjoyment may also improve, given that psychological distress decreased due to SC. The purpose of the current (post-hoc) study was, therefore, to explore the effect of SC compared to CAU on the course of sexual interest and enjoyment, using data from the above mentioned RCT. Another purpose was to examine whether the effect of SC was moderated by having an unmet sexual health need and by the presence of a psychiatric disorder at baseline. It was hypothesized that SC targeting psychological distress also reduces problems with sexual interest and enjoyment among HNC patients.

MATERIAL AND METHODS

Study design and population

In this study, analyses were performed using data of a parallel-group RCT on the efficacy of SC among HNC and LC patients with psychological distress[15]. HNC patients and LC patients who visited the outpatient clinic of the Amsterdam University Medical Centers (Amsterdam UMC), location VU University medical center (VUmc), between 2009 and 2013 for a follow-up consultation at least one month after curative treatment were randomly allocated (1:1) by an independent person to SC or CAU. Eligible patients had psychological distress (a Hospital Anxiety and Depression Scale (HADS)[19] distress score >14, or a HADS anxiety or depression score > 7. The SC program consisted of four steps: (1) watchful waiting, (2) guided self-help via Internet or a booklet, (3) face-to-face problem-solving therapy, and (4) specialized psychological interventions and/or psychotropic medication. The four steps focused on psychological distress and not specifically on sexuality. Patients who did not recover after a SC-treatment step (HADS anxiety or depression score remained above 7) proceeded to the next step in the SC program. A detailed description of the study design and SC program can be found elsewhere[14,15]. Informed consent was obtained prior to any data collection. The study was approved by the Medical Ethics Committee of Amsterdam UMC, location VUmc, was registered in the Netherlands Trial Registration (NL1758)[14] and conducted according to the principles of the Declaration of Helsinki. More information on the eligibility criteria, randomization procedure and sample size calculation can be found in previous publications[14,15].

Data

All patient-reported outcome measures (PROMs) were collected at baseline (T0), after the SC-intervention period (time depended upon duration of the SC program) or control period

(4 months) (T1), and 3, 6, 9, and 12 months after T1, using paper and pencil or OncoQuest, a touch screen computer-assisted data collection system[20,21]. On average, time between T0 and T1 was comparable[15].

Primary outcome

The patient-reported outcome measure was the 'Sexuality' symptom subscale, part of the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire, HNC-specific module (EORTC QLQ-H&N35)[22-24]. This subscale contains two questions on sexual interest and enjoyment: "During the last week have you felt less interest in sex?" and, "During the last week have you felt less sexual enjoyment?". Both items are scored on a four-point scale ("not at all", "a little", "quite a bit", "very much"). The scores of these two items are averaged and then transformed into a scale ranging from 0-100, with higher scores implying less sexual interest and enjoyment. A score higher than 10 on this subscale indicates an unmet need for help in this domain (cut-off = 10)[24].

Other outcomes

Sociodemographic and clinical variables

Information on age (continuous), gender (male, female), marital status (married/living together, unmarried/divorced/widow), years of education (continuous) and employment status (paid job, no paid job) was collected by means of self-report questionnaires. Information about tumor location (lip/oral cavity/oropharynx, hypopharynx/larynx, other), tumor stage (I, II, III, IV), and type of treatment (surgery, radiotherapy, chemoradiation, surgery + radiotherapy, surgery + chemoradiation, surgery + chemotherapy) was obtained from medical records.

Psychological distress

The HADS is a 14-item psychometrically sound, self-assessment scale for measuring distress (total HADS score) with two subscales, anxiety (HADS-A) and depression (HADS-D), developed for non-psychiatric patients. The total HADS score ranges from 0 to 42, the subscales from 0 to 21, where higher scores represent more distress[19,25]. HADS at baseline was assessed by telephone or by means of OncoQuest[20,21]. The presence of a psychiatric (depressive or anxiety) disorder was assessed by telephone using the Composite International Diagnostic Interview (CIDI)[26], a comprehensive, structured interview designed for the assessment of mental disorders such as anxiety and depression by trained lay interviewers.

Health-related quality of life (HRQOL)

A global quality of life (QOL) scale and five functional scales (physical, role, emotional, cognitive and social) were assessed with the EORTC Quality of Life Questionnaire Core 30 questions (EORTC QLQ-C30); a cancer specific questionnaire. All scales and single items

were linearly transformed into a score from 0 to 100, with a higher score indicating a higher level of functioning. The questionnaire has shown good psychometric properties in cancer patient populations[23,27].

Statistical analyses

All analyses were performed using SPSS version 20 (IBM Corp., Armonk, NY). Sociodemographics, clinical characteristics, HADS scores, CIDI diagnosis, and QOL measurements of the study sample (at baseline) were summarized using descriptive statistics. Independent samples t-tests and $\chi 2$ tests were used to examine whether randomization of the HNC patients had resulted in a balanced distribution of sociodemographic and clinical characteristics, global QOL and all functioning domains across SC and CAU. Independent samples t-tests were also used to measure differences between SC and CAU in sexual interest and enjoyment at each time-point. An absolute difference in sexual interest and enjoyment ≥ 10% of the instrument range was considered clinically meaningful[28]. A linear mixed model (LMM) was used to compare differences in the course of sexual interest and enjoyment between SC and CAU, with fixed effects for intervention, time-point and their two-way interaction, and a random intercept for subject. To control for a potential confounding effect of differences in sexual interest and enjoyment at baseline between the two interventions, an adjusted LMM was used where sexual interest and enjoyment at baseline was added as a fixed covariate to the previous model. Additionally, two other adjusted LMM's were used to investigate the effect of SC on the course of sexual interest and enjoyment with two potential moderators: a psychiatric disorder at baseline (based on the CIDI) and having an unmet sexual health need at baseline (sexuality score > 10[24], using a random intercept for subjects, fixed effects for intervention, time-point, moderator, and all two-way and three-way interactions. For all analyses missing data were excluded analysis-by-analysis rather than listwise and a p-value of < 0.05 was considered statistically significant. The data were analyzed on an intention-to-treat basis.

RESULTS

Sample characteristics

Sexuality data were unavailable for all 9 LC patients (Figure 1). Of the remaining 147 HNC patients, 134 patients (67 in the SC and 67 in the CAU group) provided a baseline score (T0) on the sexuality subscale. Patients in the SC group scored significantly better on sexual interest and enjoyment at baseline (T0): 39.5 versus 51.7; $p = 0.040$. They also scored significantly better on the HADS-total, HADS-D and the EORTC QLQ-C30 social functioning subscale, see Table 1.

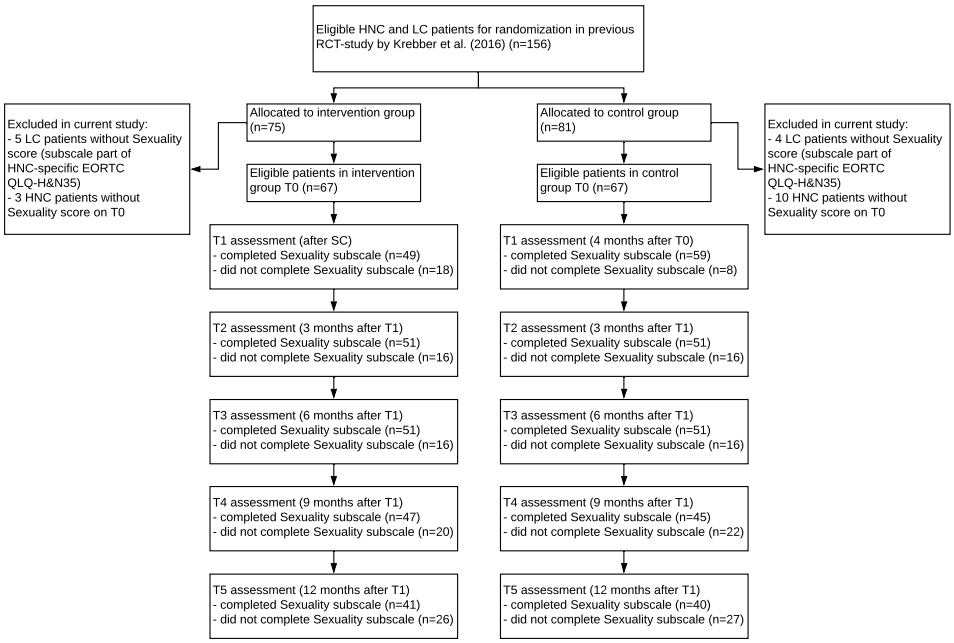

Figure 1. CONSORT flow diagram.

Table 1. Patient characteristics at baseline.

	Intervention (n = 67)	Control (n = 67)	Total (n = 134)	p-value
Age (mean, SD)	62.5 (8.5)	61.1 (9.9)	61.8 (9.2)	0.37
Gender				0.86
Male	44 (65.7%)	42 (62.7%)	86 (64.2%)	
Female	23 (34.3%)	25 (37.3%)	48 (35.8%)	
Paid job				0.86
Yes	22 (32.8%)	24 (35.8%)	46 (34.3%)	
No	45 (67.2%)	43 (64.2%)	88 (65.7%)	
Marital status				0.57
Married/living together	49 (73.1%)	45 (67.2%)	94 (70.1%)	
Unmarried/divorced/widowed	18 (26.9%)	22 (32.8%)	40 (29.9%)	
Years of education				0.29
5-10	33 (49.3%)	24 (35.8%)	57 (42.5%)	
11-16	30 (44.7%)	38 (56.7%)	68 (50.8%)	
17-21	4 (6.0%)	5 (7.5%)	9 (6.7%)	
Tumor location				0.079
Lip/oral cavity/oropharynx	29 (43.3%)	42 (62.7%)	71 (53%)	
Hypopharynx/larynx	21 (31.3%)	14 (20.9%)	35 (26.1%)	
Other head and neck cancers	17 (25.4%)	11 (16.4%)	28 (20.9%)	

Table 1 continued.

	Intervention (n = 67)	Control (n = 67)	Total (n = 134)	p-value
Tumor stage				0.22
Unknown	7 (10.4%)	2 (3.0%)	9 (6.7%)	
I	13 (19.4%)	17 (25.4%)	30 (22.4%)	
II	15 (22.4%)	9 (13.4%)	24 (17.9%)	
III	9 (13.4%)	13 (19.4%)	22 (16.4%)	
IV	23 (43.3%)	26 (38.8%)	49 (36.6%)	
Tumor treatment				**0.005**
Surgery	11 (16.4%)	19 (28.4%)	30 (22.4%)	
Radiotherapy	22 (32.8%)	12 (17.9%)	34 (25.4%)	
Chemoradiation	5 (7.5%)	18 (26.9%)	23 (17.2%)	
Surgery + radiotherapy	25 (37.3%)	14 (20.9%)	39 (29.1%)	
Surgery + chemoradiation	4 (6.0%)	3 (4.4%)	7 (5.2%)	
Surgery + chemotherapy	0	1 (1.5%)	1 (0.7%)	
Time since treatment				0.65
< 7 months	26 (38.8%)	23 (34.3%)	49 (36.6%)	
7-12 months	10 (14.9%)	14 (20.9%)	24 (17.9%)	
> 12 months	31 (46.3%)	30 (44.8%)	61 (45.5%)	
Anxiety or depression disorder (CIDI)				0.42
Yes	14 (20.9%)	19 (28.4%)	33 (24.6%)	
No	53 (79.1%)	48 (71.6%)	101 (75.4%)	
HADS (mean, SD)				
Total	17.5 (5.2)	19.5 (5.8)	18.5 (5.6)	**0.030**
Depression	8.28 (3.6)	9.96 (3.7)	9.62 (3.6)	**0.009**
Anxiety	9.18 (3.6)	9.58 (3.7)	9.38 (3.7)	0.53
EORTC QLQ-C30 (mean, SD)				
Global quality of life	59.5 (19.8)	55.5 (19.5)	57.46 (19.7)	0.24
Physical functioning	71.6 (20.9)	70.7 (20.8)	71.16 (20.8)	0.79
Role functioning	62.2 (26.7)	55.5 (26.0)	58.83 (26.5)	0.14
Emotional functioning	58.3 (26.1)	56.3 (22.6)	57.30 (24.3)	0.65
Cognitive functioning	71.4 (27.3)	70.6 (24.5)	71.02 (25.9)	0.87
Social functioning	71.9 (25.2)	58.7 (27.1)	65.30 (26.9)	**0.004**
EORTC QLQ-H&N35 (mean, SD)				
Sexuality subscale	39.6 (34.6)	51.7 (33.6)	45.65 (34.5)	**0.040**
Unmet sexual health need (sexuality subscale > 10)				0.068
Yes	46 (68.7%)	56 (83.6%)	102 (76.1%)	
No	21 (31.3%)	11 (16.4%)	32 (23.9%)	

Significant differences ($p < 0.05$) are presented in bold font.

SD standard deviation, *CIDI* Composite International Diagnostic Interview, *HADS* Hospital Anxiety and Depression Scale, *EORTC QLQ-C30* European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, *H&N35* Head and Neck specific module.

Effect of SC on sexual interest and enjoyment post-intervention

When comparing differences in sexual interest and enjoyment between SC and CAU per time-point, patients in the SC group scored statistically and clinically better post-intervention (T1) (34.7 versus 54.2; p = 0.004). However, when correcting for the baseline difference in sexual interest and enjoyment, no significant within-subjects change from baseline (T0) to post-intervention (T1) was found (p = 0.37).

Effect of SC on the course of sexual interest and enjoyment

LMM corrected for the between-group baseline difference in sexual interest and enjoyment showed that the course of sexual interest and enjoyment over time-points did not differ between SC and CAU groups (time-point * intervention: p = 0.85), see Figure 2. Of the patients, 76.1% had an unmet sexual need at baseline, and 24.6% had a psychiatric disorder, see Table 1. Neither having a psychiatric disorder at baseline (time-point * intervention * psychiatric disorder: p = 0.59) nor an unmet sexual health need at baseline (time-point * intervention * sexuality: p = 0.64) moderated the effect of SC on the course of sexual interest and enjoyment.

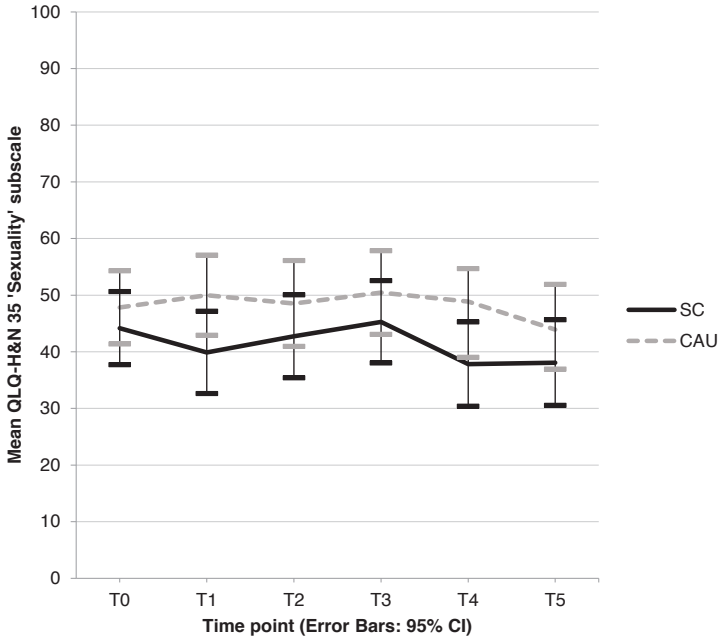

Figure 2. Effect of SC (Stepped Care) and CAU (Care As Usual) on sexual interest and enjoyment from T0 (pre-intervention) to T5 (12 months follow-up), corrected for between-group baseline differences, with 95% confidence intervals. Higher scores represent less sexual interest and enjoyment.

DISCUSSION

A substantial number of HNC patients were found to have an unmet sexual health need. SC did not reduce problems with sexual interest and enjoyment at any of the follow-up measurements compared to CAU, after correcting for baseline differences. Also, moderator analyses showed that patients with an unmet sexual health need at baseline and patients with a psychiatric disorder at baseline had no greater benefit from SC. These findings suggest that mere alleviation of illness-related psychological distress through SC is insufficient to effectively improve sexual interest and enjoyment in HNC patients, implying that interventions specifically targeting sexuality are needed for (HNC) patients who experience sexual problems.

The latter suggestion is supported by a study of Hummel et al.[29] that demonstrated that internet-based cognitive behavioral therapy directed at sexual functioning in breast cancer survivors with sexual dysfunction significantly reduced sexual problems and body image concerns. Online therapy was guided by a psychologist and specifically tailored to the sexual problems of each patient. Another study evaluated a telephone counseling intervention to improve psychosocial outcomes including sexual dysfunction in early stage breast cancer patients. Sexual functioning only improved in the intervention group, where sexual functioning was deliberately targeted[30]. The active control group (without sexual counseling) showed no improvement in sexual functioning.

Considering these findings, it can be concluded that interventions targeting psychological distress do not co-alleviate sexual problems in cancer patients. Interventions directed at sexuality address both psychological and sexual issues and possibly also their interaction. Thus, an integral approach – specifically targeting psychological and sexual issues together - is recommended for mental health care in cancer patients.

Strengths of this study are the randomized controlled design, the long follow-up period, inclusion of an active control group, and use of LMM which enables use of all collected data. A major limitation was that sexuality was assessed with two items only, since the RCT from which the data were adopted did not specifically focus on sexuality[15]. Validity of these items and sensitivity to change may be limited.

Future research may incorporate a more comprehensive and valid measure of sexual function (assessing problems as well as wellbeing) in interventions for (HNC) cancer patients and their partners. Such a sexual health questionnaire is currently being developed according EORTC guidelines[31,32]. When the psychometric qualities of this measure are established, it can be used to evaluate interventions or to tailor and monitor care. Given the substantial

unmet sexual health need and the importance of sexuality to general health, HNC patients and their partners should be asked whether they experience sexual problems and want referral for help[33-35].

Conclusion

A substantial number of HNC patients have unmet sexual health needs. SC targeting psychological distress does not reduce problems with sexual interest and enjoyment in these patients. Interventions specifically targeting sexuality are needed for patients who experience sexual problems.

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